UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY

PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No.: 2419

Docket No.: 1:13-md-2419 (RWZ)

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THIS DOCUMENT RELATES TO ALL CASES AGAINST THE BOX HILL DEFENDANTS

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BOX HILL DEFENDANTS' MOTION FOR LEAVE TO FILE MOTIONS FOR SUMMARY JUDGMENT

Pursuant to the Court's February 3, 2017 Order (Doc. 3301), the Defendants, Box Hill Surgery Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC (collectively, the "Defendants" or "Box Hill Defendants"), by and through counsel, move for leave to file motions for summary judgment, with supporting memoranda of law and concise statements of material facts¹, on the following issues:

- The Box Hill Defendants complied with the recognized standard of acceptable professional practice²;
- 2. The level of "due diligence" Box Hill completed prior to purchasing medication from NECC did not cause an outcome which would not otherwise have occurred;
- 3. The standard of care permitted the Box Hill Defendants to purchase medications from NECC without patient-specific prescriptions, and patient-specific prescriptions would not have prevented the fungal meningitis outbreak;

¹ These underlying motions, concise statements of material facts, and memoranda of law are in the process of being prepared, and the Box Hill Defendants may supplement this Motion for Leave by filing that material, if necessary.

² This motion corresponds to a forthcoming *Daubert* motion seeking to exclude all opinions by the PSC's witnesses regarding the requisite standard of care applicable to the Box Hill Defendants.

- 4. NECC's actions were a superseding, intervening cause that relieves the Box Hill Defendants from any liability for the Plaintiffs' damages, as a matter of law;
- 5. The Plaintiffs' Massachusetts Consumer Protection Claim is not a viable claim based on the law;
- 6. The Plaintiffs are not entitled to recover punitive damages as a result of the Box Hill Defendants' actions; and
- 7. The Plaintiffs' recoverable medical expenses are limited to only those reasonable and necessary expenses that are either paid or payable by the individual Plaintiffs or third party payors, excluding the amount of any charges subject to contractual adjustments or write-offs.

The Box Hill Defendants should be given leave to file the motions for summary judgment listed above, for the following reasons:

- 1. The factual record establishes that NECC represented to potential purchasers that its processes and products fully complied with the recognized standards applicable to compounded medications. As such, Box Hill would have learned the same, if asked. Thousands of other providers, including some of the nation's most prestigious institutions, purchased pharmaceuticals from NECC. Dr. Bhambhani had purchased drugs from NECC for years without experiencing a contaminated product or outbreak of meningitis. It was not reasonably foreseeable that NECC would provide contaminated methylprednisolone acetate ("MPA") resulting in an "unprecedented" multi-state outbreak of fungal meningitis.
- 2. Since NECC's actions were not reasonably foreseeable, the doctrine of superseding, intervening cause relieves the Box Hill Defendants from any liability for the Plaintiffs' damages. Absent reasonable foreseeability of an intentional act, the Box Hill

Defendants cannot be held jointly and severally liable for the Plaintiffs' damages. There is no proof that NECC intentionally contaminated the MPA at issue, or that any intentional act by NECC was reasonably foreseeable.

- 3. The standard of care did not require the use of patient-specific prescriptions, but even if they did, specific prescriptions would not have prevented the eventual outbreak. In addition, the acts of NECC that led to the contamination involved criminal activity, which gave rise to the intervening, superseding cause.
- 4. Although the PSC disclosed witnesses stating that the Box Hill Defendants deviated from the requisite standard of care, the witnesses' opinions are irreconcilable with the conduct of a substantial number of providers in their very own communities and nationally. A witness offering the opinion that the norm is an aberration is completely unreliable, and falls short of the foundational requirements for expert testimony set forth in Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).
- 5. There is no proof, much less the required evidence that the Box Hill Defendants acted "with an evil or rancorous motive influenced by hate... to deliberately and willfully injure" the Plaintiff patients in purchasing MPA from NECC and injecting it into their patients.

 Accordingly, the law of Maryland bars all claims for punitive damages against the Box Hill Defendants.
- 6. The undisputed facts establish that even if the Box Hill Defendants had completed all the various elements of "due diligence" that the PSC's professional witnesses claim were required, the Box Hill Defendants, acting reasonably just like thousands of others, would have purchased medications from NECC, just like they had done for years without incident, and the resulting fungal meningitis outbreak would not have been averted.

- 7. There is no dispute that various settling defendants and nonparties were negligent. Plaintiffs pleaded the same, and in some instances offered expert reports and testimony supporting those pleadings. Likewise, the Plaintiffs cannot dispute that at least some of these negligent actors, such as NECC, Liberty, and UniFirst, among others, caused the Plaintiffs' alleged injuries.
- 8. Massachusetts law is clear that there can be no cause of action in these cases for alleged violations of Massachusetts consumer protection laws.
- 9. Maryland law is well-settled that recoverable medical expenses in healthcare liability actions are limited to those that are necessary and reasonably related to the alleged negligence, and paid or payable by the Plaintiffs or third party payors. Plaintiffs are not permitted to recover the gross amount of charges, which fails to take into account contractual adjustments or write-offs.
- 10. If granted, several of these motions for summary judgment will either significantly reduce the number of issues remaining for trial or will be dispositive of all issues affecting the Box Hill Defendants, making their participation at trial completely unnecessary.
- 11. The issues are ripe for determination as a matter of law because the parties have thoroughly developed the factual record, including depositions of all testifying opinion witnesses on these common issues.
- 12. Consideration of these issues at the summary judgment stage will prevent the parties and the Court from unnecessarily extensive motion *in limine* practice.
- 13. The issues should not be left to the jury's consideration, as there are no genuine disputes as to the material facts, and

14. Plaintiffs' counsel is expected to file a motion for leave to seek summary judgment. The parties will be able to brief and argue the issues on a consistent timetable and schedule that will permit the Court's resolution of the issues prior to trial.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of September, 2017, I served the above Motion upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby
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